

CMS Coordination and Maintenance Committee Meeting

September 28, 2006, Baltimore MD

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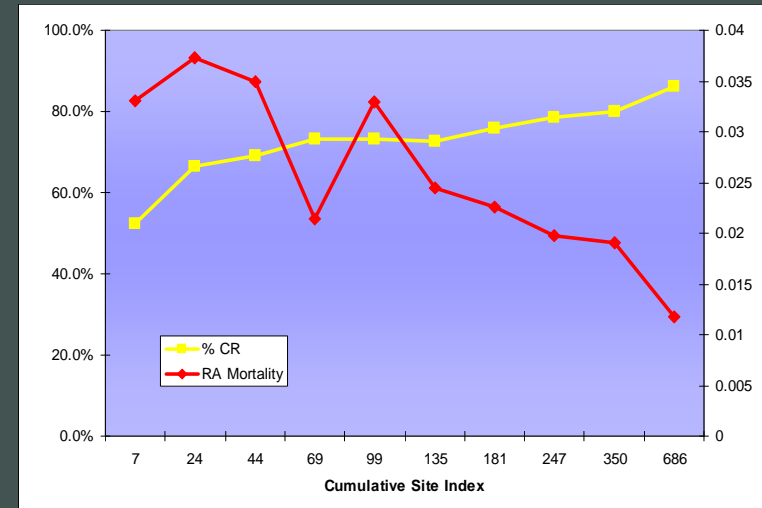
SPY

Vascular angiography using florescent properties of generic dye in conjunction with proprietary high speed digital infrared photography.

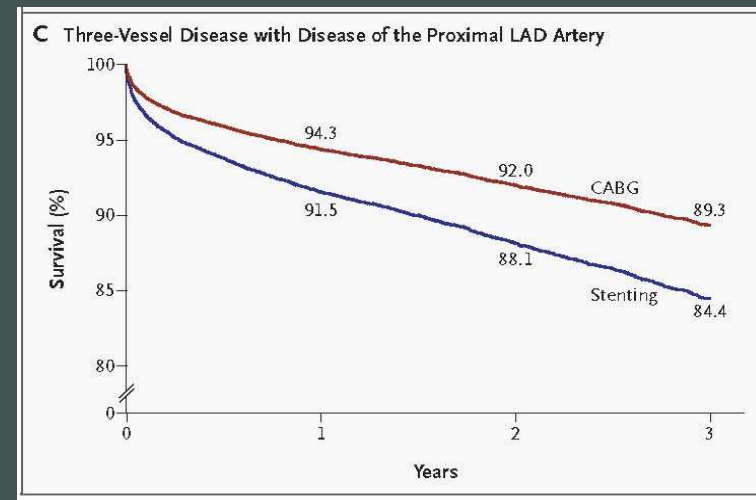
Coronary Artery Bypass Today

- > 350,000 Procedures/yr
- > 800 hospitals
- ~ 3400 active US surgeons
- ~ 75% on-pump, 25% OPCAB

➤ **Significant decline in RA OM**
(Ferguson, Circulation 2004)

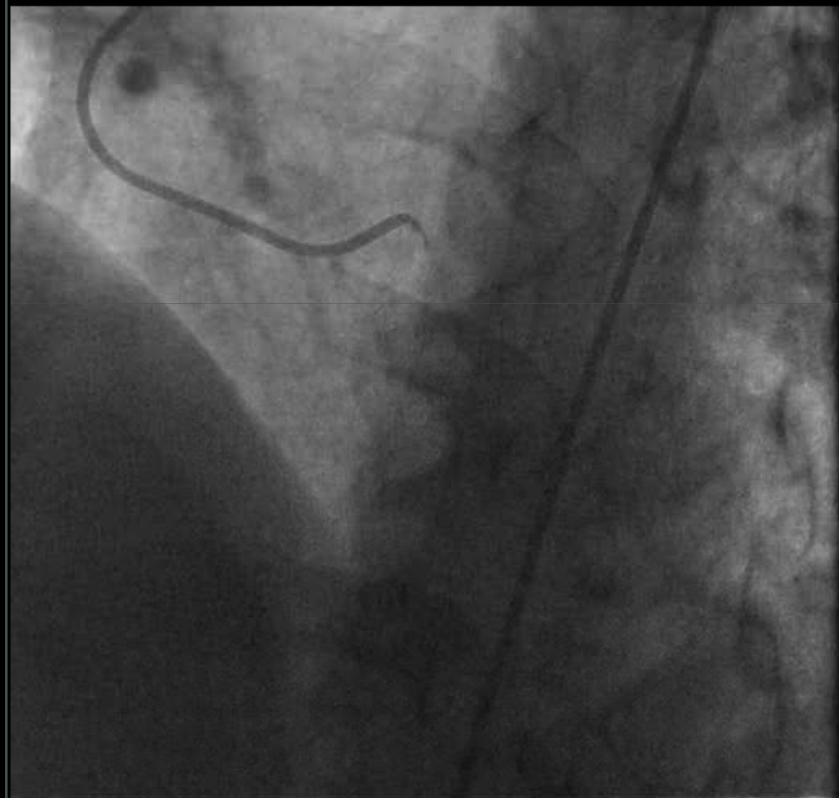


➤ **Sustained Survival benefit**
(Hannan, NEJM 2006)



Cardiac Surgery Patients Today

Lossy compression - not intended for diagnosis



Normal coronary arteries

Lossy compression - not intended for diagnosis



Diseased Coronary Arteries

Possible Clinical Benefits of Intra-operative Angiography in CABG

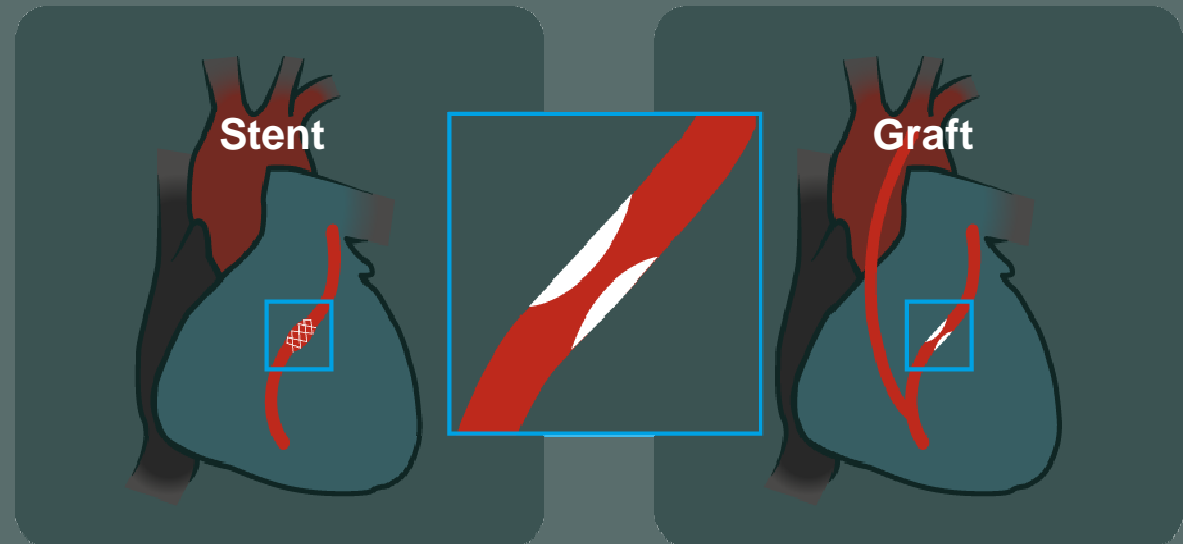
- **ANATOMY:** Optimize Procedure Plan
 - Locate and assess target vessels
- **EFFICACY OF REVASCULARIZATION:** Optimize Results
 - Assess bypass graft patency visually
 - Evaluate distal outflow
 - Anastomotic Revision/Repair
 - Re-positioning/revising graft/anastomosis
- **PHYSIOLOGY:** Document physiologic characteristics
 - Collateral flow, competitive flow, vessel size
 - Assess microvascular perfusion to coronary bed
 - Determine need and location for adjunctive therapies (TMR, genetic/proteomic therapies)

SPY

Real time visual
imaging

Coronary Artery Bypass Surgery

FDA cleared device
(Substantially equivalent to X-ray angiography)



100%
validation

<10%
validation

**Have surgeons not imaged intra-operatively
because the technology didn't exist
or because there was no (perceived)
clinical need?**

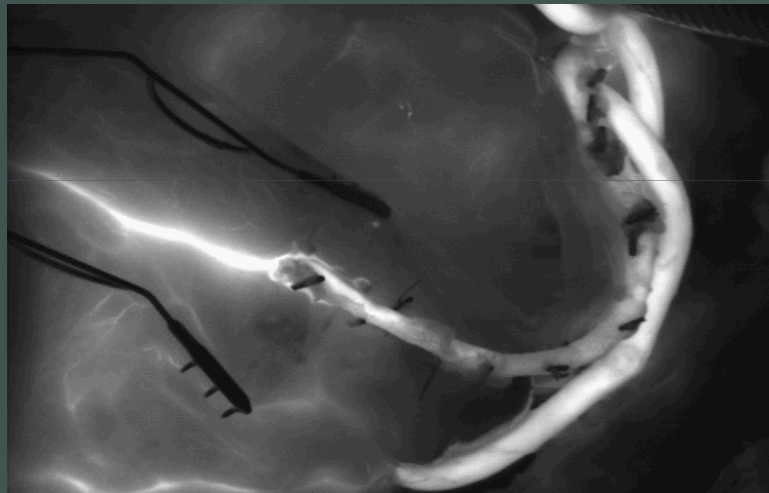
Intra-operative Fluorescence Vascular Angiography



Occluded Graft



Revised Graft



- 2000 + patient clinical experience (2000-2004)
- US clinical experience (2005/06)
1700 pts / 5000 + grafts in US
- 11 peer-reviewed journal publications
- Early adoption: 50 Centers (US)

Would Imaging Improve CABG Quality?

Graft patency is the major determinant of freedom from repeat intervention after CABG.

PREVENT IV –

- reintervention rate over 3 years higher in patients with occluded grafts angiographically at 1 year (*Alexander, JAMA 2006; 294:2446-54*)
- perioperative MI associated with poorer outcome at 2 years (*Yau, 2006*)
- Technical errors in bypass graft construction by the operating surgeon and/or endothelial factors are primarily responsible for early failures.

Would Imaging Improve CABG Quality?

Revision Rate:

- 4.2% of grafts images intra-operatively with SPY Angiography had significant problems and required major anastomotic revision and 3.5% required minor revision

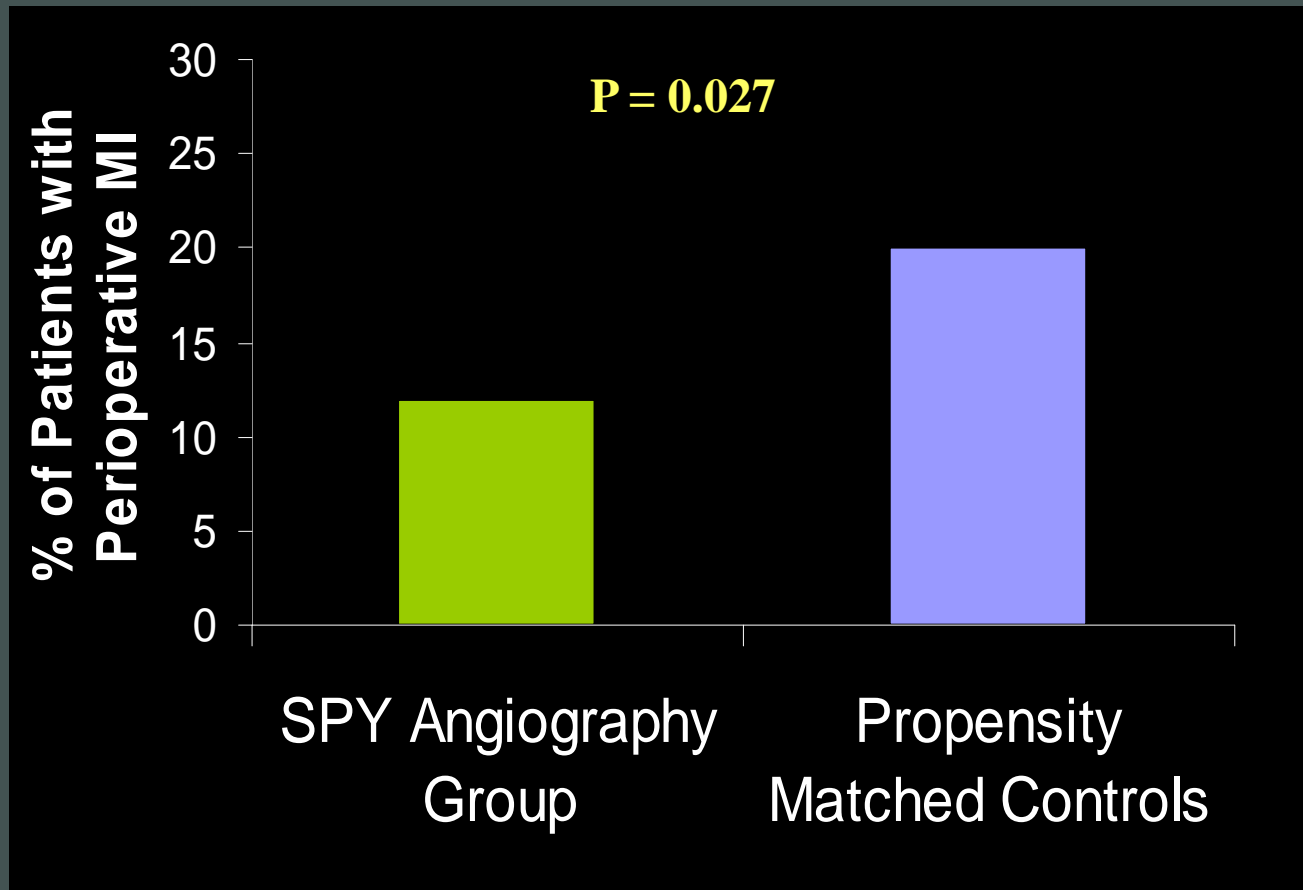
Post-op Angiographic Follow up (6 pts):

- Sensitivity - Peri-anastomotic lesions with >50% stenosis were observed in three grafts; sensitivity for detection was 100%
- Specificity - There were no false positives, and specificity for >50% stenosis was also 100%



Desai, ND. Journal of the American College of Cardiology. 2005; 46:1521-5)

Reduction in Myocardial Injury During CABG



192 Matched patients in the SPY angiography group had significantly less perioperative MI (12.0% versus 20.3% in controls)

Work Flow & Resource Allocation: Image Acquisition

Off-Pump Procedures

1. Pre LAD
2. LIMA to LAD (Additional in-situ)
3. Free Grafts (1 image per graft)
4. Proximal Anastomosis

Average of 6 image
sequences per patient

On-Pump Procedures

1. Pre LAD
2. LIMA to LAD Post (Additional in-situ)
3. Free Grafts (1 image per graft)
4. Proximal Anastomosis
5. LIMA to LAD Post w/beating heart

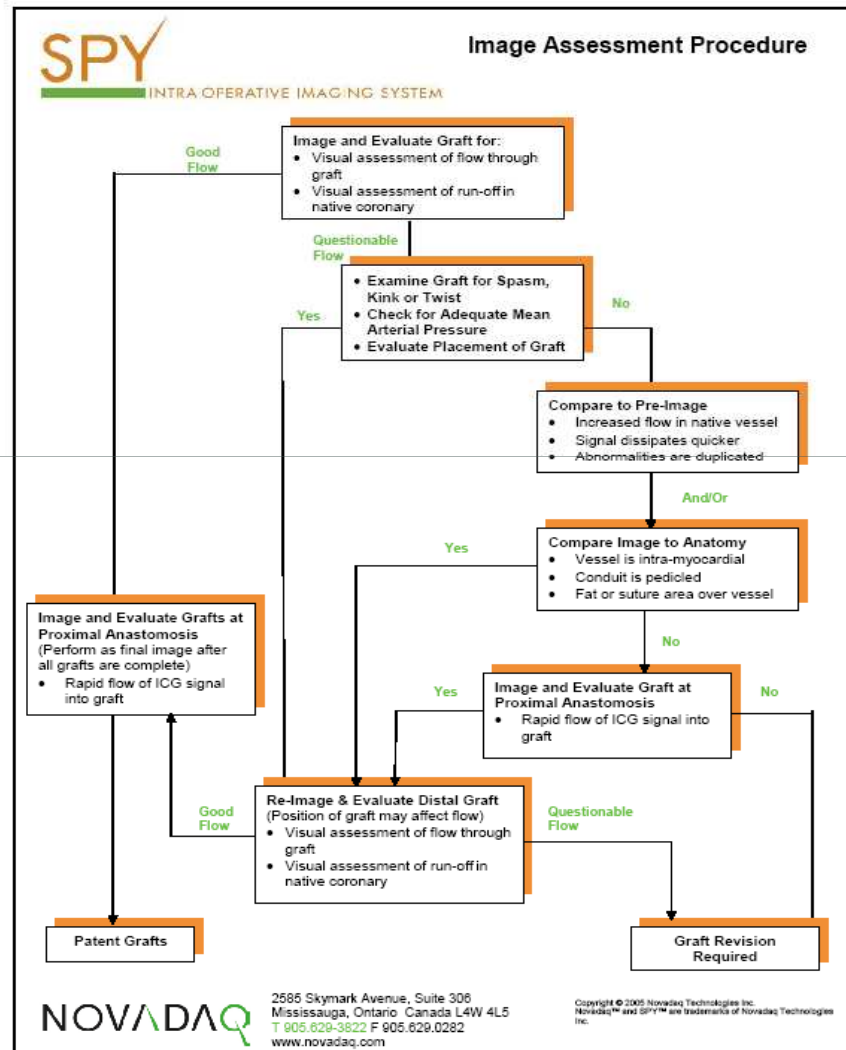
On-Pump Procedures (Direct-To-Graft Injection)

1. Pre LAD
2. Free Grafts (1 image per graft)
3. LIMA to LAD Post (Additional in-situ)
4. Proximal Anastomosis
5. LIMA to LAD Post w / beating heart

Work Flow & Resource Allocation

| Resource Activity | Resource | Per Sequence | Work Effort |
|--|---|--------------------|--------------------|
| System Setup/Drape | Circulating Nurse, Scrub Nurse | n/a | 10 - 20 min |
| Injection Preparation | CN, Anesthesiologist &/or Perfusionist | | |
| Image Capture | Surgeon, CN, Anesthesiologist | 2-3 minutes | 30 - 42 min |
| Image Assessment | Surgeon | 3-5 minutes | |
| Procedure Completion/ Documentation | Surgeon/ CN | n/a | 10 - 12 min |
| Records Archive | Circulating Nurse | | |
| Total Time (average) | | 5-8 minutes | 50 - 74 min |

Work Flow & Resource Allocation: Image Interpretation



**3-5 Minutes
per Sequence**

Post-Market Clinical Data

VICTORIA Multi-Center Clinical Registry : *Visual Interpretation of Completeness and Technical Operative Results using Intra-operative Arteriography in Coronary Bypass Surgery*

- 12 sites
- 1500 Patients
- Unique clinical and image database:
 - underlying clinical disease status
 - perfusion
 - collateral flow
 - competitive flow

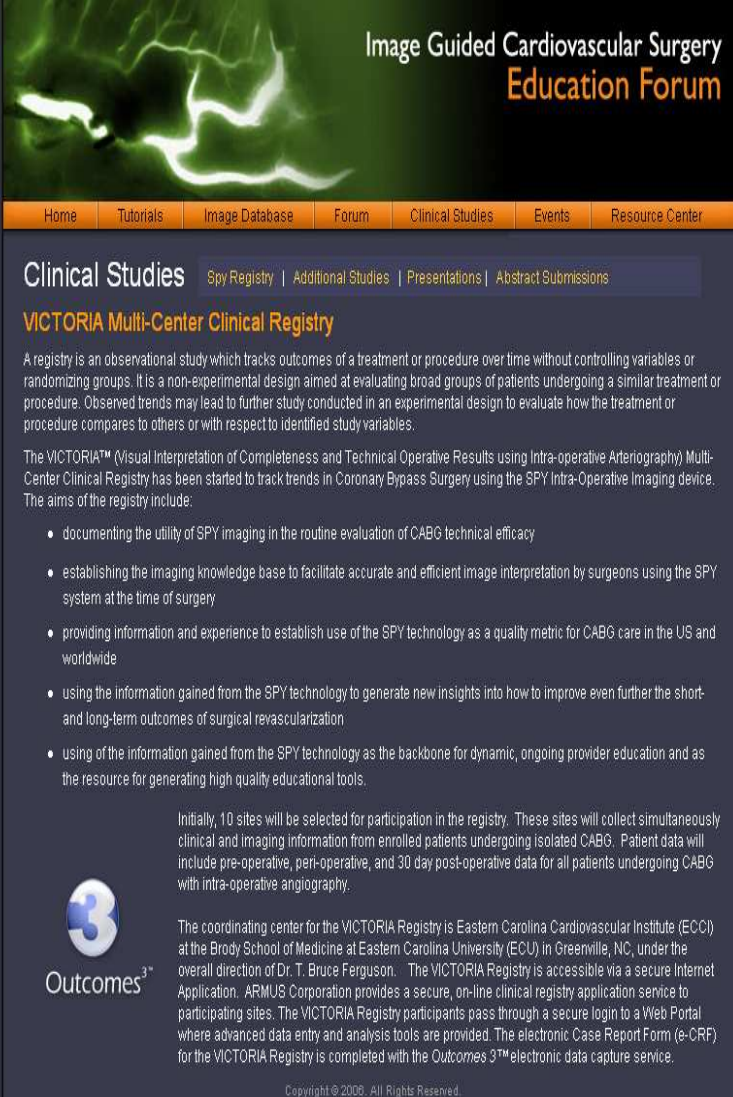


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VICTORIA Multi-Center Clinical Registry

A registry is an observational study which tracks outcomes of a treatment or procedure over time without controlling variables or randomizing groups. It is a non-experimental design aimed at evaluating broad groups of patients undergoing a similar treatment or procedure. Observed trends may lead to further study conducted in an experimental design to evaluate how the treatment or procedure compares to others or with respect to identified study variables.

The VICTORIA™ (Visual Interpretation of Completeness and Technical Operative Results using Intra-operative Arteriography) Multi-Center Clinical Registry has been started to track trends in Coronary Bypass Surgery using the SPY Intra-Operative Imaging device. The aims of the registry include:

- documenting the utility of SPY imaging in the routine evaluation of CABG technical efficacy
- establishing the imaging knowledge base to facilitate accurate and efficient image interpretation by surgeons using the SPY system at the time of surgery
- providing information and experience to establish use of the SPY technology as a quality metric for CABG care in the US and worldwide
- using the information gained from the SPY technology to generate new insights into how to improve even further the short- and long-term outcomes of surgical revascularization
- using of the information gained from the SPY technology as the backbone for dynamic, ongoing provider education and as the resource for generating high quality educational tools.

Initially, 10 sites will be selected for participation in the registry. These sites will collect simultaneously clinical and imaging information from enrolled patients undergoing isolated CABG. Patient data will include pre-operative, peri-operative, and 30 day post-operative data for all patients undergoing CABG with intra-operative angiography.

 Outcomes³

The coordinating center for the VICTORIA Registry is Eastern Carolina Cardiovascular Institute (ECCI) at the Brody School of Medicine at Eastern Carolina University (ECU) in Greenville, NC, under the overall direction of Dr. T. Bruce Ferguson. The VICTORIA Registry is accessible via a secure Internet Application. ARMUS Corporation provides a secure, on-line clinical registry application service to participating sites. The VICTORIA Registry participants pass through a secure login to a Web Portal where advanced data entry and analysis tools are provided. The electronic Case Report Form (e-CRF) for the VICTORIA Registry is completed with the Outcomes 3™ electronic data capture service.

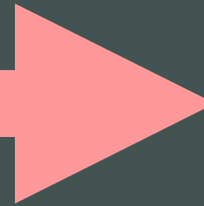
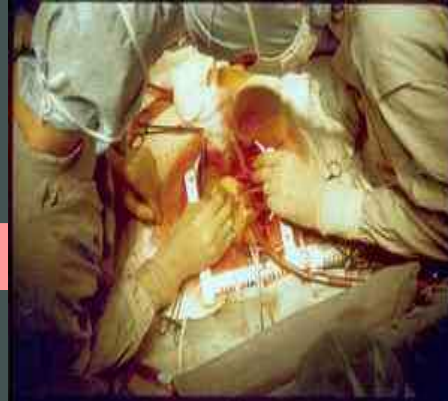
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Current Status of SPY in CABG Practice

- 97% Correlation of SPY IFVA with X-ray Angiography
- 4 - 8% Graft Revision Rate with use of SPY IFVA
- 41% Reduction in Myocardial Injury Rate (Desai)
- 11% SPY Rate of Utilization within CABG Cases at early adoption sites (range 5% - 100%)
- 50 US Centers (Sept. 2006)
- 1500 Patients - VICTORIA Multi Center Clinical Registry

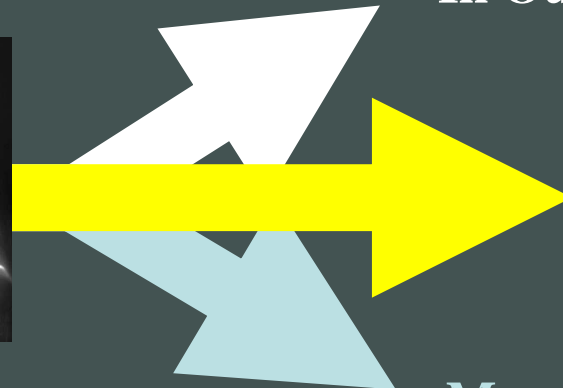
New Paradigm in CABG

Current CABG:
“Memory-Guided” and
“Judgment-Assessed”



**Incremental Improvement
In Outcomes And Quality**

**“Image-guided
CABG”**



**Directed, Patient-
Specific Adjunctive
Therapies (TMR)**

**Myocardial, Endothelial
Perfusion Biology**